

AO 120 (Rev. 08/10)

<b>TO:</b> <b>Mail Stop 8</b> <b>Director of the U.S. Patent and Trademark Office</b> <b>P.O. Box 1450</b> <b>Alexandria, VA 22313-1450</b>	<b>REPORT ON THE</b> <b>FILING OR DETERMINATION OF AN</b> <b>ACTION REGARDING A PATENT OR</b> <b>TRADEMARK</b>
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In Compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been filed in the U.S. District Court \_\_\_\_\_ for the District of Delaware \_\_\_\_\_ on the following

☐ Trademarks or ☒ Patents. ( ☐ the patent action involves 35 U.S.C. § 292.);

DOCKET NO. <b>21-538-LPS</b>	DATE FILED <b>4/14/2021</b>	U.S. DISTRICT COURT for the District of Delaware
PLAINTIFF <b>DUCHESNAY INC., SHIONOGI INC., and QUATRX PHARMACEUTICALS COMPANY</b>		DEFENDANT <b>HETERO LABS LIMITED, HETERO LABS LIMITED UNIT-V, HETERO DRUGS LIMITED, and HETERO USA INC.</b>
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
<b>1 8,642,079</b>	<b>2/4/2014</b>	<b>QUATRX PHARMACEUTICALS COMPANY</b>
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In the above—entitled case, the following patent(s)/ trademark(s) have been included:

DATE INCLUDED	INCLUDED BY <input type="checkbox"/> Amendment <input type="checkbox"/> Answer <input type="checkbox"/> Cross Bill <input type="checkbox"/> Other Pleading	
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1		
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In the above—entitled case, the following decision has been rendered or judgement issued:

DECISION/JUDGEMENT  <b>Consent Judgment</b>
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CLERK <b>John A. Cerino</b>	(BY) DEPUTY CLERK	DATE <b>11-17-2021</b>
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Copy 1—Upon initiation of action, mail this copy to Director    Copy 3—Upon termination of action, mail this copy to Director  
 Copy 2—Upon filing document adding patent(s), mail this copy to Director    Copy 4—Case file copy

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

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DUCHESNAY INC., SHIONOGI INC., and  
QUATRUX PHARMACEUTICALS COMPANY,

Plaintiffs,

v.

HETERO LABS LIMITED, HETERO LABS  
LIMITED UNIT-V, HETERO DRUGS  
LIMITED, and HETERO USA INC.,

Defendants.

C.A. No. 21-538-LPS

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DUCHESNAY INC., SHIONOGI INC., and  
QUATRUX PHARMACEUTICALS COMPANY,

Plaintiffs,

v.

HETERO LABS LIMITED, HETERO LABS  
LIMITED UNIT-V, HETERO DRUGS  
LIMITED, and HETERO USA INC.,

Defendants.

C.A. No. 21-1130-LPS

**CONSENT JUDGMENT**

Duchesnay Inc., Shionogi Inc., and QuatRx Pharmaceuticals Company (“Plaintiffs”) and Hetero Labs Limited, Hetero Labs Limited Unit-V, Hetero Drugs Limited, and Hetero USA Inc. (“Hetero”) (Plaintiffs and Hetero collectively “the Parties”) have settled their disputes in the

above-captioned actions by a settlement agreement (the “Settlement Agreement”). Now the Parties, by their respective undersigned attorneys, hereby stipulate and consent to entry of judgment and an injunction in these actions as follows:

1. Hetero has admitted that United States Patent Nos. 8,642,079 (“the ’079 patent”); 6,245,819 (“the ’819 patent”); and 8,236,861 (“the ’861 patent”) are patentable, valid and enforceable in connection with the Osphena<sup>®</sup> NDA.

2. Hetero has admitted that, unless pursuant to a license from Plaintiffs, the manufacture, use, offer for sale, sale, or importation of the Hetero ANDA Product in the United States prior to the expiration of the ’079 patent, the ’819 patent, and the ’861 patent, would infringe one or more of the claims of the ’079 patent, the ’819 patent and the ’861 patent.

3. Except as provided in the Settlement Agreement, Hetero will not challenge or otherwise dispute or contest, or assist others, whether directly or indirectly, in challenging or otherwise disputing or contesting the infringement, patentability, validity or enforceability of any claim of the ’079 patent, the ’819 patent, or the ’861 patent in any U.S. litigation or U.S. proceeding in any U.S. court or U.S. administrative agency, including the USPTO.

4. Except to the extent specifically authorized in the Settlement Agreement, prior to expiration of the ’079 patent, the ’819 patent, and the ’861 patent, Hetero and its successors and assigns is enjoined from: (i) importing into the United States the Hetero ANDA Product; (ii) making, having made, using, selling or offering to sell in the Territory the Hetero ANDA Product; (iii) assisting, causing or otherwise encouraging any third party to import into the United States the Hetero ANDA Product; or (iv) assisting, causing or otherwise encouraging any third party to make, have made, use, sell or offer to sell in the United States the Hetero ANDA Product.

5. Compliance with this Consent Judgment may be enforced by Plaintiffs and their successors in interest, or assigns, as permitted by the terms of the Settlement Agreement.

6. This Court retains exclusive jurisdiction to enforce and supervise performance under this Consent Judgment and the Settlement Agreement.

7. The above actions, including any claims, counterclaims and affirmative defenses, are hereby dismissed without prejudice and without costs, disbursements or attorneys' fees to any party.

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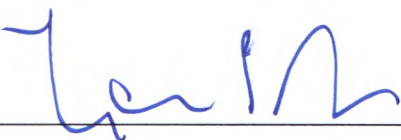
(404) 653-6400

*Attorneys for Plaintiffs*

*Duchesnay Inc., Shionogi Inc., and QuatRx  
Pharmaceuticals Company*

**IT IS HEREBY SO ORDERED.**

Dated: 11/17/21

  
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United States District Judge  
District of Delaware